September 7, 2004

Ms. Pamela B. Schweikert, Director of Compliance
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Dear Ms. Schweikert:

I would like to outline the following information to all FDA website readers interested in the outcome of the warning letter (FDA-483 WL 30-03) issued to Vision Chips, Inc.

- Vision Chips, Inc., has put in place a program to establish and maintain a quality system in compliance with FDA regulations.

- We were inspected on March 1-2, 2004 by Ms. Mei-Chen Mu from the Los Angeles District office of the Food and Drug Administration.

- The establishment inspection report (EIR) was released to Vision Chips, in August, 2004. I would like to note the following points made by Ms. Mu in the report:

    - "No FDA-483 was issued during this inspection" (page 6).
    - "No refusals were encountered during this inspection" (page 6).
    - "During this inspection, items cited in the FDA-483 were also verified to be adequately corrected. Brief description of the corrections are as follows: The firm has established and implemented Quality System, A design and development plan is being implemented, Observer 5 has been validated, Procedures were established to identify, document, verify/validate, review and approve design changes before installing the Observer 5." (pages 8-9).

- The following voluntary corrections are also noted by Ms. Mu in the EIR:

    - "The firm has established a quality system, Quality policy and objectives, quality plan, quality system procedures and management reviews. Procedures are included in or referenced in Quality Manual, QM Rev. 01, 9/30/03). The management representative was observed to be documented and the management review meeting agenda (held 9/11/03) was also observed" (page 7).
    - "The firm has established procedures for quality audits (Internal Quality Audits, OP 1701, Rev. 02, 1/16/04) and the last audit was observed to be completed on 1/20/04" (page 7).
    - "Design and development plan procedure has been established (Design Control, OP 0401, Rev. 05, 1/21/2004) and is observed to be implemented in the beginning stages of Observer 5.5. For the Observer 5, the firm has documented retrospective design plan, input, and output review" (page 8).
    - "I observed that the firm has completed a retrospective validation of Observer 5 program with integrated image archiving (with predetermined acceptance criteria) on 10/20/2003" (page 8).
    - "The firm 'Corrective and Preventive Actions and Effectiveness Measures' procedure, OP 1401, Rev. 06, 2/3/2003, indicates the requirements for identifying whether verification or validation is needed after a corrective and preventive action has taken place. According to [the management representative], there has not been a design change requiring re-verification or re-validation of Observer 5" (page 8).
    - "The firm has established and implemented 'Installation' procedure (Op 1901, Rev. 01, 9/30/2003). Various lower level work instructions were also established for more detailed installation and servicing procedures (i.e., 'OBserver Client Installation', WI 1912, Rev. 01 9/30/03, and 'OBserver Oracle Server Installation', WI 1913, Rev. 01, 9/30/2003). I reviewed three randomly selected completed Installation Reports (F 1901, Rev. 01) and did not observe any objectionable deficiencies" (page 8).

- "The firm has also established 'Technical Support', (OP 1902, Rev. 02, 11/24/2003). This procedure is to provide instructions for servicing provided both in person and over the phone which includes troubleshooting, maintenance and software product patches" (page 8).

Thank you, in advance, for allowing us to post this response on the FDA website.

Sincerely,

Ronald D. G. Philip, President
Vision Chips, Inc.